# This Page Is Inserted by IFW Operations and is not a part of the Official Record

### **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

### IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problems Mailbox.

#### REMARKS

Applicant respectfully requests reconsideration of this application, and reconsideration of the Office Action dated April 18, 2003 (Paper No. 5). Upon entry of this Amendment, claims 1-31 will remain pending in this application. The amendments to the claims are supported by the specification and the original claims. No new matter is incorporated by this Amendment.

\* \* \* \* \*

Claims 3, 4, 8, 9, and 12 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not adequately described by the specification. The Office Action asserts there is no description of the lighting conditions under which the pupil diameter is to be measured. The Office Action also asserts that the term "diopt" is not defined. Applicant respectfully traverses.

With respect to the word "diopt", there was not seen usage of that word for the referenced claim 12. In any event, Applicant respectfully submits that "diopt" or "diop" would be readily recognized by one of ordinary skill in the art as an abbreviation for "diopter".

As to the reference made to light conditions, it is standard procedure in the laser surgery context to use scotopic pupil size for measurement, and one of ordinary skill in the art would understand, following a review of the context of the present application, that the referenced pupil dimensions is relative to the standard pupil measurement starting point of a dim light or scotopic pupil. Attached in Appendix A are a few articles A1-A4 which illustrate that a scotopic pupil condition is the standard setting for pupil measurements.

In view of the above remarks, Applicant respectfully submits that the rejection is overcome. Hence, withdrawal of the rejection is respectfully requested.

Claims 3, 4, 8, 9, 12, 15, 19, 24, and 29-31 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully traverses.

For the reasons outlined above regarding the standard procedure of using a scotopic pupil state as the frame of reference in the context of the claimed invention, it is respectfully submitted that the claims referencing a pupil would not be considered indefinite to one of ordinary skill in the art.

As to the formula terms of claim 12, it is respectfully submitted that one of ordinary skill in the art, following a review of the disclosure of the present application, (e.g., the discussion starting on page 26 and the referenced illustrations of 4, 4A and 5E), would understand that the formula is written in the context of a mathematical description of the curvature represented. As seen from the above disclosure and illustrations the curvature profile to be generated is achieved by way of an equation written in rectangular coordinates and expressed as the difference between a paraboloid of fifth power less a paraboloid of sixth power. As an illustration of the mathematical basis from which the formula can be generated with the assistance of the discussion in the application and the reference points, reference is made to Attachment B (Calculus with Analytical Geometryby Howard Anton 1980). Pages 864-867 which illustrates the plotting of paraboloids in three dimension (second power only but illustrates the mathematical framework that exists for an understanding of what is presented in the formula set forth in the present application). Page 890 further illustrates that computer generated mesh perspectives can be utilized to present the 3-D configuration represented by the above noted formula with the plot points designated in the description.

Also, while the curvature profile equation is based on rectangular coordinates (e.g., starting with a plane of a matrix with 100 x 100 dots like a coordinate system with

origin on (0,0) that matches with the center of pupil and embracing from (-5,-5) millimeters thru (5,5) then the equation describes the surface of presbyopic profile under those boundaries in rectangular X,Y,Z coordinates), various other reference means as in polar coordinates can be used to generate the same profile based on the information provided in the present application.

Claim 15 has been amended in the present application to read --opposite sides-rather than "opposite radial sides" and is respectfully submitted to be definite.

In claim 19, the phrase "lower quarter of the depth region" has been replaced with – in a lower quarter of a depth of maximum ablation" which clearly defines the parameter in the z-axis direction being set.

Claim 30 has been amended to include functional language after "means".

In view of the foregoing explanations and claim revisions, withdrawal of the 35 USC 112, second paragraph, rejection is respectfully requested.

\* \* \*

Claim 10 was rejected under 35 U.S.C. § 102(e) as being anticipated by Largent (U.S. Pat. No. 6,312,424). Applicant respectfully traverses.

Claim 10 concerns a method of producing a presbyopic corrective cornea profile. The method includes: a) defining an internal circular zone A, having a diameter I, which represents an unablated portion of the profile, b) defining an inner annular ablated zone B, about the internal circular zone, having an outer diameter H and an internal diameter I, c) defining an intermediate annular zone C, about the inner annular ablated zone B, having an outer diameter G and an internal diameter H, d) defining an outer annular zone D, about the intermediate annular zone C, having an internal diameter G, and having an outer periphery with a diameter F, and e) establishing a presbyopic corrective cornea profile based on the zones defined in steps a) to d). Thus the zones are established to facilitate the

formation of a presbyopic corrective profile which, from the standpoint of presbyopia correction (e.g., whether alone or supplemented with hyperopic, astigmatic or myopic corrections which can also be included but in relation to the described presbyopic correction profile) maintains an internal zone unablated.

While Largent describes a method of vision correction which employs directing a laser towards a mask which modulates the energy to achieve shaped first and second regions of the anterior surface of a cornea, the mask modulates the laser such that the laser beam has different energy levels at different locations across the modulated laser beam to provide multi-focal and/or progressive vision correction. The modulated beam is directed through a lens and towards the cornea where it ablates the anterior surface of the cornea at different degrees. *See Column 3, Lines 7-25*. While Largent shows dividing the surface of the eye into annular zones, Largent teaches that each of the zones are ablated to a certain degree. For example, Largent states:

Thus, in FIG. 2 there is a central region C of the cornea which preferably has an intermediate vision correction power. If desired, the power in the central region may be progressive. The central region is circumscribed by coaxial annular regions. Thus, the annular region F provides far vision correction powers, the annular region P1 provides progressive vision correction powers, the annular region N provides near vision correction powers and the annular region P2 provides progressive vision correction powers. If desired, the regions F and N may also include progressive vision correction powers, but their primary purpose is to achieve far and near correction, respectively. Column 3, lines 52-65.

According to the method of Largent, the laser beam ablates, across the entire referenced surface of the treated eye, the respective sections to form a different ablation configuration in each zone in an effort to achieve multi-focal and/or progressive vision corrections. <u>See</u> Figures 1-3, Column 2, lines 32-45, and Column 4, lines 23-45. See also Figure 3 showing a central ablation, both near and far vision ablation rings, coupled together with progressive zone ablation rings.

Applicant's method is completely different from Largent's method. In the present invention, an internal circular zone A, which represents an unablated portion of the presbyopic corrective profile is defined. Largent neither teaches nor fairly describes this step. Largent also fails to teach or fairly suggest establishing a presbyopic corrective cornea profile based on the zones defined in the previous method steps. Since, Largent fails to teach or fairly suggest each and every element of the present invention, Largent cannot anticipate claim 10. Accordingly, the rejection is overcome and its withdrawal is respectfully requested.

\* \* \*

Claims 10, 13, and 16-23 were rejected under 35 U.S.C. § 103(a) as being obvious based on Largent in view of Dunn (U.S. Pat. No. 5,864,379). Applicant also respectfully traverses this rejection.

The deficiencies of Largent are discussed above, Dunn, in its discussion of providing an overcorrected central zone as part of its effort to correct presbyopia, fails to remedy the deficiencies of Largent. This is because Dunn, like Largent, also fail to teach or fairly suggest defining an internal circular zone A, which represents an unablated portion of a corrective presbyopic profile, and also fails to establish a presbyopic corrective cornea profile based on the zones defined in the previous method steps. In fact, Dunn is concerned with contact lenses and not laser corrected vision surgery.

Furthermore, there is nothing in the teachings of Largent or Dunn which would motivate those of skill in the art to modify the combined teachings of the prior art to arrive at the present invention. Hence, since Largent and Dunn, even when combined, fail to teach or fairly suggest each and every feature of the claimed invention, they cannot render the claimed invention obvious.

Claims 5-7 and 25-29 were rejected under 35 U.S.C. § 103(a) as being obvious based on Largent in view of Shimmick (U.S. Pat. No. 6,203,539). Applicant likewise respectfully traverses this rejection. In the discussion of the rejection it is set forth "[I]t would have been obvious to relate the tissue removal of Largent to the nasal superior point, since this would amount to a mere shifting of the coordinate system the computer uses when producing an optical correction centered on the optical axis and would provide no unexpected results.

It is respectfully submitted that in view of the lack of any reference or evidentiary support for the above quoted assertion as to the obviousness of using the claimed nasal superior starting point in the context of claim 5, for example, a prima facie case of obviousness has not been established. (See **In re Lee**, 277 F.3d 1338 (Fed. Cir. 2002))

Applicant respectfully submits that the above remarks overcome this rejection. Withdrawal of the rejection is thus overcome.

\* \* \*

Claim 1-31 were also rejected under the judicially created doctrine of obviousness-type double patenting based on claims 1-56 of U.S. Pat. No. 6,302,877). Applicant respectfully requests that this rejection be held in abeyance until the present application is otherwise indicated as being allowable. Applicant will address the issue of filing a Terminal Disclaimer at that point.

\* \* \* \* \*

Applicant respectfully submits that this Amendment and the above remarks address all of the outstanding rejections in this case. Allowance of this application is earnestly solicited.

If any fees under 37 CFR §§1.16 or 1.17 are due in connection with this filing, please charge the fees to Deposit Account No. 02-4300; Order No. 032935.497723.

If an extension of time under 37 CFR § 1.136 is necessary that is not accounted for in the papers filed herewith, such an extension is requested. The extension fee should be charged to Deposit Account No. 02-4300; Order No. 032935.497723.

Respectfully submitted,
SMITH, GAMBRELL & RUSSELL, LLP

By:

Dennis C. Rodgers, Reg. No. 32,936

1850 M Street, N.W., Suite 800

Washington, D.C. 20036 Telephone: (202)263-4300 Facsimile: (202) 263-4329

Dated: October 20, 2003

DCR/BLN

### APPENDIX A

**Pupil Size and** 



Welcome to LasikInfoCenter

Pre-Surgery Considerations

Unethical Marketing Practices

Legal Resources

**About Us** 

Outside Resources

Search for:

-----

Start .

#### Lasik

Some refractive surgeons display remarkable laziness, incompetence, and ignorance with respect to one of the most fundamental pre-operative considerations of Lasik eye surgery – dim light (scotopic) pupil size.

It is widely accepted that if an individual has pupils that enlarge in dim light beyond the diameter of the proposed laser ablation, refractive surgery should not be performed. Competent surgeons go to great lengths to accurately check for scotopic pupil size, shutting off all lights in a room with the exception of a handheld penlight and measuring pupils with a ruler (or with an infrared device called a pupillometer). The reason is that as pupils enlarge in dim light to let in more light to the retina, various problems begin to occur for the large-pupilled Lasik patient. More light is now passing over the transition zone between the ablated edge of the cornea and the unablated edge. As the light dims further, light now passes over the unablated edges of the cornea. As this happens, light begins to scatter and the retina begins receiving good information from the ablated area and distorted information from the transition zone and unablated edges of the cornea. The result is debilitating haloes, glare, and double vision. It is easy to understand why this happens given the optics and physiology of the eye and how they are altered by Lasik.

Post-refractives who are experiencing low-light vision problems due to scotopic pupils exceeding the size of the ablation zone are usually told one or more of the following things by their doctor:

- 1) "The problem will go away eventually."
  (i.e., "Just wait long enough for the statute of limitations to run out so you can't sue me.")
  - 2) "You must just be the unlucky 0.1% who experiences problems." (Note: Such figures are often pulled out of thin air.)
- 3) "There is no proven correlation between pupil size and post-op glare symptoms."

  (Note: This is true because no formal study on the issue has ever been

(Note: This is true because no formal study on the issue has ever been done, although it is a widely recognized phenomenon.)

4) "You're just being too picky about your eyesight. The problem is in your mind, not your eyes."

The following articles demonstrate that the issue of pupil size has been known and discussed in mainstream medical literature for years. Your doctor should have known about the need to check pupil size accurately and not proceeded with the operation if you were a high-risk candidate.

Jack T. Holladay, MD, MSEE, The High Cost of Inaccurate Pupillometry, FACS, Rev. ОРНТН., 3/02	"The need to detect the patients with large pupils as a part of the refractive evaluation makes precise pupiliometry measurements crucial."
Brian Chou, O.D., and Brian S. Boxer-Wachler, M.D., <i>The Role</i> of Pupil Size in Refractive Surgery, 2/01.	"Night vision disturbances have been reported in over 25% to 35% of patients after PRK and Lasik using a 6.0 mm abiation zone. These disturbances are more frequent with smaller abiation diameter, larger pupil diameter, and greater attempted correction."

D. James Schumer, M.D., Harkaran S. Bains, COMT, Kevin L. Brown, O.D., <i>Dark-</i> Adapted Pupil Sizes in a Prospective Evaluation of Laser in situ Keratomileusis Patients, J. REFRACT. SURG., Vol. 16, 3/4 (supp.) 2000, p.S239-41.	"Pupil size clearly has an effect on the functional vision of the refractive surgery patientIn addition to a lack of consensus and reported studies about magnitude of the effect that pupil size has on visual outcome, there are no adequate nomograms to guide surgeons when treating these patients."
	Ch.12 - Preoperative Myopic and Hyperopic LASIK Evaluation, pp.131-2 "High myopes not only commonly have reduced best-corrected vision, but also night glare, and it is important to evaluate these candidates carefully, taking into account the corneal thickness, pupil size, and planned optical zone when
Jeffery J. Machat, M.D., <u>Excimer Laser Refractive</u> <u>Surgery,</u> 2nd Ed., SLACK Inc., 1999, ISBN # 1556423861.	counseling them."  Lasik Complications, p.397
	"Night glare is a result of a pronounced form of spherical aberration, with the pupil diameter in dim light exceeding that of the effective optical zone created. Patients complain of halos, starbursts, and a general reduction of qualitative vision in conditions of reduced lilumination."
	Ch. 2 - Patient Selection and Preoperative Workup, Table 2-1
Howard V. Gimbel et. al., <u>Lasik</u> Complications: Prevention and	"Patients with large pupils need to be forewarned of the possibility of night vision difficulties. Especially important in high corrections. Corneal surgery may not be advisable."
<u>Management,</u> SLACK inc., 1999, ISBN#1556423926. (1.0 MB)	Ch. 2 - Patient Selection and Preoperative Workup, p.17 "Pupil measurements may indicate that a patient will have night vision disturbances if the pupils are widely dilated in dim light, and those patients should be warned that they are at higher than average risk for this side effect of LASIK or PRK."
Lucio Buratto & Stephen F. Brint, <u>Lasik: Surgical</u> Techniques and Complications, 2nd ed. 10/1/99, ISBN # 1556424329.	"Recent studies demonstrate that as the pupil Increases in size with increasing darkness, there is a corresponding decrease in the contrast sensitivity, particularly at the lower contrast."  **Preoperative Pupillometry in LASIK, p. 41**  "In order to provide a good refractive and visual outcome under all light intensities, it is necessary to perform an ablation with an optic zone proportional to the pupil diameter. As a result, the preoperative measurement of the pupil diameter under scotopic light is very important. Pupil diameter ca be measured by a number of methodsin 10% of our patients, the scotopic pupillometry was greater than or equal to 7.0 mm; "blindly" performing an operation on these patients may therefore be disadvantageous for both the patient and the surgeon."  **Optical Zone, Pupil Diameter, and Requested Correction, p.92**  "It is commonly known that the occurrence of halos and night glare can arise from the optical properties governed by the size of the treatment zone and the pupil diameter in dim light conditions, presumably because the scotopic pupil dilates beyond the diameter of the optical surgical zone."  **Ablation Zone, Pupil Diameter, and Requested Correction, p. 92**  "The issue of ablation zone diameter (sometimes improperly called "optic zone") is certainly crucial in pianning LASIK treatment. The appropriate ablation diameter has to be decided, taking into account different parameters such as attempted dioptric correction, residual corneal thickness, and pupil diameterPupil diameter can easily be measured using infrared**
	pupiliometersThey provide pupil diameter measurements under scotopic conditions, which is the way pupillary diameter has to be measured, because complaints by patients regarding night vision when the pupil dilates. As a general rule, pupils measuring 6.0 mm in diameter are very unlikely to have visual disturbances at night, at least for low to medium myopic corrections. Larger pupils require larger ablation diameters to avoid visual disturbances, and higher attempted corrections require the same because of the greater ligh scattering that occurs at the ablation edge."  p. 226  "Giare, especially at night, is one of the greatest problems, seen more

	• •	
	frequently in patients with large pupils and high corrections. The abrupt edgeslope created in high corrections defracts light, thus inducing halosThis complication is more important in those patients with unusually large resting pupil diameters. The scotopic pupil diameter should be measured preoperatively and the patient counseled based on this and the amount of planned correction. This complication is due to an accentuated form of spherical aberration, with the diameter of the pupil under low luminance exceeding the effective optical zone createdPatients with a disproportional large pupil compared to the optic zone should be avoided."	
	p.244 - Night Glare and Halos  "Night vision disturbances should be considered a very Important side effect of laser surgery. The risk of this complication must be screened pre-operatively through the measurement of pupil diameter, and adequate ablation strategies must be applied to minimize this side effect which, once occurred, is very difficult to deal with! personally have some patients who had to change their profession because they were unable to drive at night after surgeryOnce induced, these disturbances are very difficult to solveBefore surgery, the preoperative visit should include pupil measurements under different light conditions! personally use the following guidelines: Once a patient is found to have very large pupils in dim illumination (>7.0 mm), I discourage him or her from undergoing laser refractive surgery, or at least I inform him or her of the great risk of night vision problems, regardless of the correction."	
Jack T. Holladay, MD, MSEE, REV. OPHTH., What We Should Really Tell LASIK Patients, 5/99.	"Unlike the haloes that result from a too-small optical zone, this problem affects every patient who undergoes an excimer laser procedure to some extent. Like the halo problem, the oblate dilemma is worst for patients whose pupils dilate widely at night."	
Jack T. Holladay, MD, MSEE, Deep R. Dudeja, MD, Joanne Chang, OD, Functional Vision and Corneal Changes after LASIK determined by contrast sensitivity, Glare Testing, and Corneal Topography, J. CATARACT & REFRACT. SURG., Vol. 25, 5/99, pp.663-669.	"Functional vision changes do occur after LASIK. The optical quality of the cornea is reduced and the asphericity becomes oblate. Changes in functional vision worsen as the target contrast diminishes and the pupil size increases. These findings indicate that the oblate shape of the cornea following LASIK is the predominant factor in the functional vision decrease."	
Brian S. Boxer Wachler, MD & Ronald R. Krueger, MD, MSE, Agreement and Repeatability of Infrared Pupillometry and the Comparison Method, OPHTH., 2/99, Vol. 106, No. 2, pp. 319-23.	"in photorefractive keratectomy, there is an important relationship between the corneal ablation diameter and the pupil diameter. When the pupil dilates larger than zone of treatment, myopic blur is expected, which could reduce visual functionEven when the ablation zone equals the pupil diameter, off-axis light, such as a street light, may still cause glareAs glare has been shown clinically to be related to overall patient satisfaction with photorefractive keratectomy, attention to the patient's pupil diameter is importantthe ablation diameter should be no smaller than the nocturnal pupil diameter to minimize glare and halosThere appears to be a need for accurately determining the pupil diameter in a dark environment as patients with pupils larger than 6 mm should be counseled about the high risk of glare and halos or a larger ablation diameter may be selected."	
Michael Colvard, MD, Preoperative Measurement of Scotopic Pupil Dilation Using an Office Pupillometer, J. CATARACT & REFRACT. SURG., 12/98.	"Patients with widely dilating pupils at low levels of illumination may be dissatisfied with the quality of their vision after keratorefractive surgery. Careful measurement of scotopic pupil dilation should therefore be an integral part of the preoperative evaluation."	
Ocular Surg. News, Pupil Measurement in Scotopic Light is Made Possible, 12/98.	"The [Colvard Pupiliometer] makes it possible to fiag patients whose pupils dilate widely in low-light conditions. This information can be used to counsel these patients about the potential for night-driving related glare, halos, and/or monocular diplopla, or to recommend against laser refractive surgery altogether – or at least until refinements in excimer laser technology make larger treatment zones possible."	
Leslie B. Sabbagh, Pupillometer Can Improve Refractive Patient Selection, OPHTH. TIMES, 9/15/98, Vol.23, #18.	"Pupiliary size in scotopic conditions is an often overlooked but critical element in refractive surgery outcomes. For the past few years, some refractive surgeons have cautioned that patients with pupils that dilate widely in low light conditions (especially night driving) may be extremely unhappy with their vision, even though they have 20/20 Snellen acuity. Unfortunately, it seems their warnings have largely gone unheeded."	
M. Alaa El Danasoury, MD, FRCS, Prospective Bilateral Study of Night Glare After LASIK with Single Zone and Transition Zone Ablation, J. REFRACT. SURG., Vol. 14, 9/10/98.	"Distortion of vision in the form of glare and halos is one of the major concerns after excimer laser refractive surgery. Glare and halo symptoms typically become worse at night, when the pupil dilates and more peripheral light rays enter the eye from the untreated zone."	

Lynda Charters, Corneal Refractive Surgery Has Its Limits, OPHTH. TIMES, 8/15/98.	"in the presence of a small pupil, defocused pericentral rays will be blocked by the Iris, resulting in higher degrees of contrast. As pupil size increases, the amount of defocused pericentral light rays admitted into the posterior segment increases, resulting in contrast degradation at the macuia."
Carlos Martinez, Effect of Pupillary Dilation on Corneal Optical Aberrations After PRK, ARCH. OPHTH., 8/98. (1.0 MB)	"We agree with Hersh et. al. that surface smoothing, an increase in ablation zone diameter, and the use of peripheral blend zones may in the future improve the optical results of PRK. Increasing the diameter of the ablation zone could push the edge of the ablated region peripherally beyond the edge of the entrance pupil. However, many patients undergoing PRK are young, with an average pupiliary size of 7.5 mm; for such patients, this approach would require a large ablation diameter, and a large ablation zone would also increase the sagittal dephth of a spherical ablation."
Peter Hersh et. al., WESTERN J. MED., Excimer Laser Refractive Surgery, 7/1/98.	"Complications of refractive surgical procedures such as PRK and LASIK can be considered primarily optical or "physical." Optical complications include glare, halo, decreased contrast sensitivity, and diplopla. Glare and halo symptoms are likely due to the optical effects of light passing through the border between the centrally treated and peripherally untreated cornea. An eye with a larger pupil would be more likely to manifest the symptoms of glare and halo, especially at night when the pupillary diameter is greatest."
Editor's Note - Response to Bill Nixon, J. CATARACT & REFRACT. SURG., 3/98, vol. 24, #3, pp. 291- 294.	"William Nixon has raised an important issue regarding screening for pupil size In prospective refractive surgery patients. Measurement of pupil size may be the most frequently neglected facet of the refractive surgery evaluation. This is partly because measurement of pupil size has been difficult and unreliable with the old "coat-pocket" pupil gauges and partly because many surgeons have not appreciated the absolute necessity of considering this parameter preoperativelyrecent reports in the literature should heighten surgeons' awareness of the importance of preoperatively identifying patients with widely dilating pupils."
	Preoperative Evaluation, p.125 "Measuring the size of the pupil in dim illuminations is important to avoid glare problems postoperatively"
ioannis G. Palilikaris & Dimitrios S. Siganos, <u>Lasik</u> , 1998, Slack, Inc., ISBN # 1556423233.	Advanced Visual Function Testing in LASIK, pp. 320-29  "Halos and visual loss at night may result from negative clearance, a condition where the pupil naturally dilates larger than the optical zoneTo quantify the degree of negative clearance, accurate measurement of the pupil under dim (mesopic) conditions is requiredIf pupil dlameters are accurately measured preoperatively, patients at risk of halos may be appropriately counseled or directed toward another procedurein conclusion, it is incumbent upon practitioners to understand basic principles of vision testing, such as contrast sensitivity, and have an appreciation for the mechanisms behind optical aberrations that arise from refractive surgical procedures."
Lucio Buratto & Stephen F. Brint, <u>Lasik: Principles and</u> <u>Techniques</u> , 1998, ISBN # 1556423713.	Lasik - Preoperative Considerations, pp.24-25 "Pupil size should be measured in both scotopic and mesopic lighting conditions. Young patients with large pupils should be advised of potential glare, halo, and night driving problems following refractive surgery. One has to weigh the benefits versus these difficuities in highly myopic patients requiring small optic zones."
	Patient Selection and Preoperative Considerations, Ch. 2, p.45 "Pupil size becomes more relevant when considering refractive procedures in patients with very large pupils in low light conditions. These patients need to understand the increased risk of glare or halos and may opt for future
Peter S. Hersh et. al., <u>Refractive Surgery</u> , Thieme Medical Publishers, 1998, ISBN # 0865777594. (1.3 MB)	, ,
Hear Dr. Jack Holladay speak at the 1997 International Society of Cataract and Refractive Surgeons conference in San Francisco. (Part i - 683 KB) (Part ii - 771 KB) (you can ilsten to these .mov files with the free Quicktime software package)	vision problems under low levels of illumination."
	"While it has come to my attention that many refractive surgeons screen for pupil size, it is also true that many do not. Regardless, I do not believe there

	•	
Letters, Pupil Size in Refractive Surgery, J. CATARACT & REFRACT. SURG., Vol. 23, 12/97.	exists a shared set of guidelines used to determine the eligibility of potential patients who, like myself, have both large pupils under low-light conditions as well as moderate to severe myopla. It is for the sake of these potential patients that I ask you to consider reporting on my case and others like it. Additionally, I ask the favor that my case be addressed because of my desperate need to learn of any and all options that might allow me to again live a normal life."	
Peter Hersh, Results of Phase III Excimer Laser Photorefractive Keratectomy for Myopia, ОРНТН. 10/97, Vol. 104, #10.	"Glare and halo may be caused by corneal haze and by a variety of changes in corneal contour, including edge effects and topographic irregularities in the treatment zone. Such optical side effects usually are worse when the pupil is larger than the edge of the functional optical zone and when the pinhole effect is least, most commonly at night. It has been suggested that glare, halo, and other optical aberrations might be diminished using a larger ablation zone because this would place the edge of the zone outside most pupils."	
Raymond A. Applegate, OD, PhD, Refractive Surgery, Optical Aberrations, and Visual Performance, J. REFRACT. SURG., 5-6/97.	"It was recognized a decade ago that visual outcomes were improved by correctly centering the procedures on the entrance pupil and using the largest central zone possible."	
	"Patients with smaller optical zones may often complain of visual aberrations at night, but not usually during the day. Aberrations are described as starbursts, halos, and/or blur. It is not uncommon for some patients to experience the full range of these effects. These night vision phenomena increase in incidence with any treatment zone decentration."	
Ollvia N. Serdarevic, <u>Refractive</u> <u>Surgery: Current Techniques</u> <u>and Management</u> , Igaku-Shoin Medical Publishers, 1997, ISBN # 1556422865.	Ch. 7, Prevention and Management of Complications of Photorefractive Keratectomy, David S. Gartry, Ronald Stasiuk, & David Robinson, p.87.  "Aberration effects are possible as a result of the demarcation between the central ablation zone and the untreated cornea. Early studies documented these effects. It was found that when the surgery is particularly effective, a halo around lights at night may be noted, especially by patients with large pupils those patients with a large change in refractive status experienced the greatest halo effecta high correlation between pupil size and halo effectpatients with larger pupils were much more likely to complain of halo.	
	p.34 "One should refrain from operating on individuals with very large pupils (>6 mm) without at least forewarning them about the possible effects on night driving and glare."	
Harold Stein, Albert Cheskes, & Raymond Stein, <u>The Excimer -</u> <u>Fundamentals and Clinical Use,</u> 2d ed., 1997, SLACK Inc.	pp. 82-3 "The problem with small optical zones is that if the pupil dilates, especially at night, halos can be produced as a result of refraction of light at the edge of the abilation."	
	p. 143 "Halo EffectSymptoms are more apt to occur at night when dilation of the pupil allows light transmission at the edge of the ablation zone. Persistent halos rarely occur and are usually related to large pupils or a decentered ablation."	
Jonathan Carr & Peter Hersh, Patient Evaluation for Refractive Surgery, In Dimitri Azar, ed., <u>Refractive Surgery,</u> 1997, ch. 7, pp.101-8. (1.3 MB)	"Measurement of the diameter of the entrance pupil in both light and dark conditions may identify patients who have very large pupils, which may exacerbate edge effects of the optical zone following refractive procedures (for example, glare, halo, and the starburst phenomenon)."	
Leon Strauss & Dimitri T. Azar, Optics Rediscovered for the Keratorefractive Surgeon, in Dimitri Azar, ed., Refractive Surgery, 1997, ch. 8, pp.113-24. (1.8 KB)	"Size of the entrance pupil (the image transmitted through the cornea) should be estimated in brightly and dimly lit conditions. If the entrance pupil is larger than the optical zone in dim but photopic conditions, then an annulus of cornea surrounding the optical zone will transmit rays to the fovea."	
Clinical Results of Excimer Laser Photorefractive Keratectomy for the Treatment of Myopia, in Dimitri Azar, ed., Refractive Surgery, 1997, pp.448-49.	"The primary determinants of the halo effect appear to be the ablation-zone diameter, pupil size, and the amount of induced refractive change. The halo effect after excimer laser PRK is generated by the differential refraction of light through the treated (flattened) central cornea and the untreated (still myopic) paracentral cornea. When the pupil is larger than the diameter of the ablation zone, light rays passing through the paracentral cornea, which are normally blocked by the iris, now fall on the perifoveal retina and create a defocused annulus of light around the focused image on the fovea. This optical aberration results in a myopic blur circle superimposed on the corrected image from the central cornea. Therefore, under scotopic conditions, when the pupil dilates, the halo effect tends to be more pronounced, particularly in patients with small abiation-zone diameters."	



Col. Thomas Mader, MD, Bilateral PRK with Intentional Unilateral Undercorrection Performed on an Aircraft Pilot, J. CATARACT & REFRACT. SURG., Vol. 23, 3/97.	"Glare and ghost images, which have been well documented following PRK, may become even more prominent with increased pupil size. Optical zone diameters must be at least as large as the entrance pupil to preclude glare at the fovea and larger than the entrance pupil to preclude parafoveal glare. If a PRK patient fixates on a bright light source, out-of-focus light from the edge of the abilation area may form a halo around the image of the object. Thus, optical aberration at night following PRK may be especially bothersome."	
Mihai Pop, <i>Large Pupils Cause</i> a Devilish Problem: Halos, EYEWORLD, 11/96, p.46.	"Individuals with refractive errors greater than -4D with scotopic pupil sizes of mm or larger are absolutely not indicated for excimer laser surgery because the abiation zone of currently available excimer lasers does not exceed 6 mm. The onus is on the surgeon to choose the right patient."	
Stephen Trokel, MD, Enlargement of the PRK Optical Zone, J. CATARACT & REFRACT. SURG., 11/96.	"These results may cause significant loss of corrected and uncorrected visual acuitles as well as deterioration in visual quality, including glare, halos, and ghost images with decreased contrast acuity and contrast sensitivity. These complications occur in younger patients, even those with normal corrected and uncorrected visual acuities under standard testing conditions, because PRK may create an optical zone that is too small to fill the relatively larger entrance pupil of younger eyes."	
PRK Complications and Management (p.11), Physician's Training Manual, Visx Star S2 ExcImer Laser, 1996, P/N 0030- 1724, Rev. A.	"Night Giare, Haioes, and image GhostingCan be seen in young patients with large diameter pupils in dim illumination (some patients can have 9 mm dim illumination pupil). Always check pupil prior to ablation and warn patient of this possibility."	
PRK for Nearsightedness with Astigmatism (p.14), Physiclan's Training Manual, Visx Star S2 Excimer Laser, 1996, P/N 0030- 1724, Rev. A.	"Please remember that it is important to check pupil diameter in light and dim conditions. Under certain circumstances, the minor axis of the elliptical ablation that is created to correct the astigmatism can be 4.5 mm. If a patient has large pupils in dim lighting conditions there is the potential for difficulty with vision in poor light conditions following PRKa."	
	p.95 "Understanding that patients with large pupils are at higher risk for night visual disturbances enables us to reformulate our treatment parameters with certain laser systems."	
Jeffery J. Machat, M.D., Excimer <u>Laser Refractive</u> Surgery, SLACK inc., 1996, ISBN # 1556422741.	p.98 "A pupil that expands beyond the ablative zone will create halos if symmetric, crescents of glare if asymmetric, and if significant, monocular diplopia can be created."	
	p.189 "Halos are directly related to pupil size in dim light exceeding the effective optical zone size, a pronounced form of spherical aberration."	
	p.388 "Night glare is a result of a pronounced form of spherical aberration, with the pupil diameter in dim light exceeding that of the effective optical zone created. Efforts to increase the diameter of the optical zone utilized are complicated by the greater depth of abiation and the formation of central islands. Patients complain of halos, starbursts, and a general reduction in qualitative vision in conditions of reduced illumination. Night glare can virtually disable extremely myopic individuals both preoperatively but especially postoperatively for night driving."	
	p.389 "in LASIK, the corneal flap acts to decrease the effective optical zonein LASIK, the tissue removed is a myopic lenticle with tapered edges which allow the flap to actually mask the peripheral area of abiation."	
Peter Hersh, Jack Holladay, Corneal Optical Irregularity After Excimer Laser PRK, J. CATARACT & REFRACT. SURG., 3/96.	"general finding of greater subjective symptomatology such as glare and halo in patients with large pupils after PRK. As the pupil dilates in low light situations, bringing the junction of the optical zone and untreated cornea over the entrance pupil, increased forward light scatter may occur with defocused rays reducing the contrast of retinal images similar to the experience with multifocal intraocular lenses. Although high-contrast Snellen acuity is not significantly affected, patients may notice glare and halo and low contrast acuity may be reduced. Future modifications in the laser abiation algorithm, such as novel surface-smoothing techniques, an increased optical diameter, and the use of peripheral blend zones, and changes in the postoperative regimen may minimize surface microirregularities overlying the entrance pupil and, thus, improve overall optical function after PRK."	
Gregory Klonos, MD, John Pallikaris, MD, <i>A Computer</i>	"If the entrance pupil is not fully covered by the ablation zone, disturbances	



Model for Predicting Image Quality after PRK, J. REFRACT. SURG., 2/96.	In night vision often are reported as starbursts and halos around bright sources of light."
Yair Alster, Dapiprazole for Patients with Night Haloes After Excimer Keratectomy, GRAEFE'S ARCH. CLIN. EXP. OPHTH., 2/96.	
O'Brart et. al., Effects of Ablation Diameter, Depth, and Edge Contour on the Outcome of PRK, J. REFRACT. SURG., 1- 2/96, Vol.12, #1. (1.1 MB)	"The combination of large pupillary excursions with small ablation diameters results in the generation of myopic blur circles. These are apparent to patients as halos around point sources of light at night. They may cause significant and persistent impairment of night vision."
Charles J. Casebeer et. al., <u>Lamellar Refractive Surgery,</u> SLACK Inc., 1996, ISBN#1556422865.	"Poor night vision and other problems were found to be associated with small optical zones. At night, a patient's pupils are dilated beyond the zone of correction, so that the edges of the ablation are uncovered. Light coming into the eye is refracted from these edges, and halos are created around point sources of light, such as lamps."
Till Anschutz, M.D., Pupil Size, Ablation Diameter, and Halo Incidence After PRK, SYMP ON CATARACT, IOL, & REFRACT SURG, 1995.	"This study found a direct correlation between pupil size and abiation diameter. On average, small abiation diameters caused more halo effectsAbiation diameter should correspond to pupil size. A 7.0 mm abiation zone is recommended for patients 20 to 30 years old, and an enlarged 8.0 mm abiation zone could help diminish halo effects in eyes with larger pupils. Preoperative pupil measurement and selection of a corresponding abiation diameter could help increase visual performance and reduce halo effects."
George Florakis & Stephen L. Trokei, Evaluation of Night Vision Disturbances, J. CATARACT & REFRACT. SURG., 5- 6/94.	"visual degradation experienced as halos or distinct rings of light may be attributed to a pupil diameter hich is greater than the clear zone diameter after abiation. This is important because the diameter and placement of the ablation zone may be ilmited by technical specifications of the laser performing the surgical procedure or by the surgeon's desire to limit the depth of ablation"  "Halos may also be due to a clear zone that is decentered from symmetrical placement around the line of site. Decentration can be a technical problem
	arising from inaccurate centration by the refractive surgeon."
Barry Winn et al., Factors Affecting Light-Adapted Pupil Size in Normal Human Subjects, INVESTIGATIVE OPHTH., 3/94.	"A further problem associated with pupil measurement is that the pupil is never entirely at rest but undergoes small, continuous oscillations known as hippus. A single "snapshot" estimate of pupil size cannot, therefore, be accepted as a reliable predictor of true mean size. instead, the pupil should be monitored continuously for a suitable period to enable a confident estimate of mean size"
Caivin W. Roberts & Charles J. Koester, <i>Optical Zone</i> Diameters for Photorefractive Corneal Surgery, investigative OPHTH, 3/93.	"Uozato and Guyton were the first to calculate the optical zone area needed to obtain glare-free distance vision in emmetropia. They stated that, "for a patient to have a zone of glare-free vision centered on the point of fixation, the optical zone of the cornea must be larger than the entrance pupil (apparent diameter of the pupil). Not only must this optical zone be without scarring and irregularity, but it must also be of uniform refractive power."
William S. Baron, Predicting Visual Performance Following Excimer PRK, REFRACT. & CORNEAL SURG., 9-10/92.	"When the ablation zone covers the entire entrance pupil, the retinal image is formed by a uniform optical system. However, if the ablation zone does not fully cover the entrance pupil, the image formed on the retina will be produced by a duplex optical system having in-focus and out-of-focus components. For an on-axis target and centered optical system, light passing through the entrance pupil's central ablated area is in-focus, and light passing through the annular untreated area is out-of-focus."
I.E. Loewenfeld, <i>Pupillary</i> Changes Related to Age, reprinted in <u>Topics in Neuro-Opthalmology</u> , H.S. Thompson, R.B. Daroof, L. Frisen, <i>et. al.</i> (eds.), Williams & Wilkins, 1979, p.129.	Many refractive surgeons, in their effort to brush off the large-pupilied patient with post-Lasik giare and halo symptoms, will tell the patient that his/her pupils will eventually shrink with age to within the laser abiation zone. This is true, but as the chart shows, the process can take several decades.

2311554

Sunday October 19, 2003



eye

Google Search The Internet:

Search WWW C Search www.drsalz

Aeri A | Biography | Publicatons | Current Projects | Procedures | Photo Gallery | Testimonials | FAQs | Contact Us | Eye Links | A Adr

eye

#### **Site News:**

CUSTOMCORNEA® Laser Surgery A Customized Laser Vision Treatment

Learn about creating the LASIK flap with the Intralase laser

My recent article on LASIK for farsightedness

Testimonial of my daughter after LASIK

The Importance of Pupil Size

Site for Sale: Laser Eye Center Exposed

Laser Surgery Battle-Worthy In Army's Eyes

LASIK, one eye at a time, click here to find out why!

Eye Doctors who have selected Dr. Salz for their surgery

Grateful patient who was advised to have LASIK at 3 other centers before seeing Dr. Salz

Why should I choose Dr.
Salz to perform my
Vision Correction (VC) or
other refractive surgery
technique?

Am I A Candidate For Laser Surgery? Click Here To Find Out.

Look at our Eye
Professionals' list to find a
Doctor near you.

LA Daily News Article -01/30/99 Laser Surgery

Aids Farsighted Patients

#### The Importance of Pupil Size

When considering refractive surgery, patients with larger pupils should be advised that they are potentially at an increased risk for night glare.

#### BY JAMES J. SALZ, MD

In last month's issue of Cataract & Refractive Surgery Today, I participated in a point/counterpoint article about the controversial topic of pupil size. It became a subject of concern to me in the early 1980s with the introduction of radial keratotomy. With that procedure, which requires optical zones of 3.0 mm (or less for some surgeons), it was obvious that the scotopic pupils would almost always be larger than the central portion of the fine scars left by the incisions. The fact that night glare, or "starbursting," would result from this procedure was accepted not as a complication, but as an almost certain side effect. I always mentioned this as a possibility in the informed consent, and softened it by stating that in most patients, starbursting would improve with time, although some may experience permanent difficulty. It remains surprising to me how infrequently this was a major problem for patients. Among the 407 patients in the PERK (Prospective Evaluation of Radial Keratotomy) study, in which adequate data were available, 37% stated they experienced glare, halos, radiating lines, or discomfort in bright light prior to their surgery. This increased to 52% at one year and the difference was statistically significant. However, only three patients felt this was severe enough to limit their night driving and all three refused surgery on their second eye. 1 My associates and I were involved in the early VISX PRK study for low-to-moderate myopia, which started patient recruitment in 1990. Pupil measurements were not required in the preoperative workup, but we mentioned glare and halos as a possible complication in the informed consent. There were reports of significant night glare in the early days of PRK, when there was concern about the risk of haze being related to the depth of the ablation. Ablation diameters of 5.0 mm and less were selected for higher corrections in order to minimize ablation depth, and halos and glare at night were frequent complications. These early reports put us on alert about the relationship between ablation depth and glare and halos, but there were very few formal studies in print.

10/19/2003



#### **CASE STUDIES**

#### Patient No. 1

The following are the results of wavefront studies performed on four of my patients who have undergone conventional LASIK using the LADARVision system (Alcon Laboratories, Fort Worth, TX). Patient No. 1 was a 28-year-old white female who was having difficulty wearing a contact lens in her right eye, but was satisfied with a contact lens in the left eye. We enrolled her in the LADARVision FDA LASIK study in 1998. Her pupils measured 7.5 mm, and her refraction was -5.75 -1.75 X 180. The required treatment zone at that time was 5.5 mm, with a 1.0-mm blend zone, for a total ablation diameter of 7.5 mm. Since the time of her 1-month postoperative examination, the patient's UCVA has remained at 20/20. She was bothered by night glare and halos and elected not to undergo surgery on her other eye, which had a refractive error of -6.00 -2.25 X 02. Although the ablation is well centered (Figure 1) and well outside her photopic 4.5mm pupil, it is apparent that if the pupil was 7.5 mm, as it would be in the dark, light striking the peripheral cornea would be outside the ablated area, likely causing glare and aberrations.

The LADARWave study of this patient's post-LASIK right eye showed RMS values of 0.32 for coma and 1.60 for spherical aberration (Figure 2). The refractive data found in these images are not accurate, as the readings reflect the power across the entire cornea for 7.5 mm, and thus include the steep area beyond the ablation. For accurate refractive data, the software can constrict the pupil to 3.0 mm. Although we do not have the preoperative wavefront image for that eye, it would probably be similar to that of the unoperated left eye (Figure 3), in which we see RMS values of 0.28 for coma and 0.71 for spherical aberration. The LASIK procedure more than doubled the patient's spherical aberration, which explains the night glare she describes in the right eye. This glare is markedly reduced when her pupil is constricted through the consensual light reflex. The LADARWave study of the left eye with the contact lens in place shows that the RMS values for both coma and spherical aberration have reduced dramatically to 0.14 and 0.11, respectively, explaining her satisfaction with a contact lens for her night vision (Figure 4).

#### Patient No. 2

The next patient was a 47-year-old white male who underwent LASIK with the LADARVision system 2 years ago. His preoperative measurements are as follows: OD -4.25 - 1.50 X120=20/20, OS -5.75 -1.25 X 90=20/20. His PupilScan (Keeler Instruments, Broomall, PA) measurements were OD 6.5 mm and OS 6.4 mm. The ablation diameters were OD 6.6 mm with a 1.0-mm blend zone, for a total of 8.6 mm. Because the patient was experiencing some night glare, the left eye had an ablation of 7.0 mm with a 1.0-mm blend zone, for a total of 9.0 mm. One year postoperatively, his UCVA is 20/15 OD, 20/20 OS, refraction OD -0.25 sphere, OS +0.75 - 0.75 X 180. His photopic vision is excellent, but he has significant scotopic glare and halos including viewing

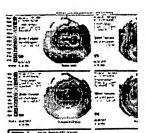


Figure 1. The postop topography of patier shows the treated riq and the untreated le

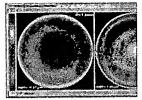


Figure 2. The LADAI study of the first par post-LASIK right eye RMS values of 0.32 fc and 1.60 for spheraberration.

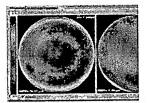


Figure 3. The LADAI study of the first pa untreated left eye sho values of 0.28 for co 0.71 for spherical abe



Figure 4. The LADAI study of the first patie eye with her contact place demonstrates reduction in RMS val spherical aberration a to 0.14 and 0.11, resp



television programming in dark, indoor rooms while at work. He has been able to control his symptoms by using Alphagan drops (Allergan, Inc., Irvine, CA) twice daily. His topography shows well-centered ablations, but LADARWave studies with his pupils at 6.5 mm show RMS values for both eyes of 0.75 for spherical aberration and 0.62 for coma. If this patient's pupils measure 5.0 mm, as they usually do after applying Alphagan, the RMS values reduce by over 60% to 0.23 for spherical aberration and to 0.25 for coma.

#### Patient No. 3

Another patient, a 32-year-old white male, was concerned about night glare because his pupils measured 6.5 mm. The refraction in his left eye was -2.25 -2.00 X 02. He had an ablation of 7.0 mm with a 1.0-mm blend zone, for a total ablation of 9.0 mm in diameter. The post-LASIK topography of his left eye is shown in Figure 5. His uncorrected vision is 20/15, and his refraction is plano. Although this patient was satisfied with the results of the procedure, he continues to experience night vision disturbances, and he waited more than 2 years before undergoing surgery on his right eye. With a 6.2-mm pupil, the RMS values for his left eye are 0.60 for spherical aberration and 0.31 for coma. With a pupil of 4.0 mm, the RMS values are again dramatically reduced to 0.02 for spherical aberration and 0.06 for coma.

In patient No.1, it is easy to understand her problems with night vision, because of the 7.5-mm pupil and an ablation diameter of 5.5 mm with a 1.0-mm blend zone; the wavefront readings give us objective confirmation of her symptoms. We can also see that in the second and third patients, simply enlarging the optical zone diameter did not completely eliminate the problems with scotopic vision. Although each had far less spherical aberration than did the first patient, both require Alphagan drops to minimize their problems with night vision. The wavefront measurements of their higher order aberrations are significantly reduced when their pupil size is diminished, giving us objective evidence of the important role of pupils. If both of these patients had a wavefront-guided ablation, rather than simply a larger ablation, their results would most likely have been even better.

#### Patient No. 4

To show that a larger diameter optical zone can at times be helpful, consider the next patient. This 31-year-old white female has 8.0 mm pupils. Her refractions were OD -5.25 D, OS -5.25 -1.00 X172. The patient underwent sequential LASIK, allowing 1 week between eyes to ensure that she was satisfied with her night vision. I created the flaps using the INTRALASE FS Laser (IntraLase Corp, Irvine, CA) and used the LADARVision 4000 to produce ablation diameters of 7.0 mm OD and 7.0 mm OS, with a 1.0-mm blend zone. Her uncorrected vision is currently 20/15 OD and 20/20 OS, and she is completely satisfied with her night vision. The LADARWave RMS measurements with pupils of 5.5 mm are between 0.23 and 0.28 for both spherical aberration and coma. These values would undoubtedly be higher if her pupils were larger, and we would like to repeat the study in the future with her pupils slightly dilated.

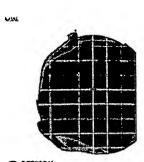


Figure 5. The postop Keratron maps of the of patient No. 3 follow mm ablation zone, 1 blend, with LADAR40 a large ablation dia



#### CONCLUSION

Surgeons who disagree with the correlation of pupil size and glare quickly cite two recent articles by Weldon Haw, MD, and Edward Manche, MD<sup>2</sup> and Mihai Pop, MD<sup>3</sup> each of which failed to find a correlation between pupils and glare. Both of these articles summarized their results in a relatively small series of patients and a correlation may have been found if more patients were treated.

There is no doubt that factors other than pupil size are important in refractive surgery, but it cannot be denied that large pupils certainly increase the risk for some patients. The challenge lies in trying to identify these patients. A simple office maneuver can confirm the importance of the pupil in reducing night glare. When a postoperative LASIK patient complains of night vision problems, I examine him or her in a completely dark, windowless refracting lane. I ask the patient to look at a single projected line of letters and tell him or her to concentrate not on the clarity of the letters, but on the glare and halos around the rectangular light. I determine which eye has the most glare and then hold an occluder in front of the other eye while shining a penlight directly into the pupil to consensually constrict the pupil in the eye that is observing the chart. Invariably, the glare significantly decreases, at times even disappearing completely. Applying a drop of Alphagan as first suggested on the Internet user's group, Keranet by Jay McDonald, MD, and retesting the patient 30 to 40 minutes later frequently minimizes night vision difficulties.

In summary, refractive surgeons should carefully measure the scotopic pupils as accurately as possible and properly advise patients with larger pupils, especially those requiring a large correction, that they are potentially at an increased risk for night glare. Wavefront testing is beginning to provide us with a method of objectively correlating the quality of night vision with measurements of higher-order aberrations. Ablation diameters as large as or larger than the scotopic pupil can reduce, but not eliminate night vision problems. Wavefront-guided ablations will hopefully minimize the increase in higher-order aberrations that frequently accompanies standard ablations, and thus improve the quality of vision for our patients.

James J. Salz, MD, practices at the American Eye Institute in Los Angeles, California. He is a consultant to Alcon and VISX. Dr. Salz may be reached at (323) 653-3800; jjsalzeye@aol.com

<sup>1.</sup> Waring, GO, Lynn MS, Gelender H, et al: Results of the prospective evaluation of radial keratotomy (PERK) study one year after surgery. Ophthalmology 92:177-198, 1985

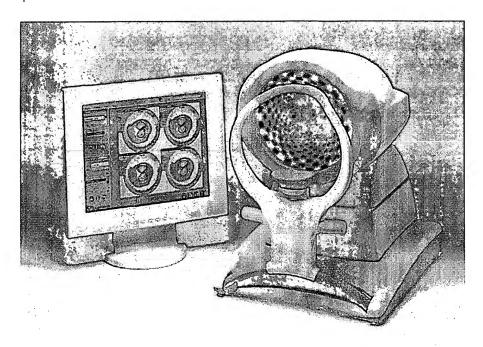
<sup>2.</sup> Haw W, Manche E: Effect of preoperative pupil measurements on glare, halos, and visual function after photoastigmatic refractive keratectomy. J Cataract Refract Surg 27:907-916, 2001

<sup>3.</sup> Pop M: Fall ISRS Symposium, November 2000, Dallas, TX

## This Page Blank (uspto)

#### **ASTRAmax**

Manufactured by LaserSight Inc.(Winter Park, FL), the ASTRAmax Integrated Diagnostic Workstation is approved by the FDA for use in the United States. LaserSight is a leading supplier of quality technology solutions for laser vision correction and has pioneered its patented precision microspot scanning technology since it was introduced in 1992. Its products include the LaserScan LSX® precision microspot scanning system, its international research and development activities related to the Astra family of products used to perform custom ablation procedures known as CustomEyes and its MicroShape(TM) family of keratome products.



The Astra family of products includes the AstraMax(TM) diagnostic workstation designed to provide prec diagnostic measurements of the eye and CustomEyes CIPTA® and AstraPro(TM) software, surgical planning tools that utilize advanced levels of diagnostic measurements for the planning of custom ablation treatments. ASTRAmax (ASTRA = AdvancedShape Technology Refractive Algorithm) is said to be the first stereo topographer available in the ophthalmic marketplace. AstraMax is an integrated refractionagnostic workstation that performs analysis of aberrations within the eye. An AstraMax integrated workstation can be utilized in both ophthalmic and optometric practices for planning ophthalmic procedures that require precise and accurate measurements of the eye. These procedures include contact lens fitting, cataract extractions, clear lens extractions, and planning for customized laser ablations. Previously, an ophthalmologist or optometrist needed to utilize at least two separate diagnost instruments to obtain the diagnostic information that the AstraMax can acquire. The diagnostic measurements from the AstraMax can be utilized for a broad spectrum of ophthalmic applications.

It is a patented three-camera imaging system featuring stereo ray tracing with polar grid target and advanced surface reconstruction algorithms. The unit provides full limbus to limbus (12 mm) coverage. ASTRAmax's uniqueness is that it provides multiple complex measurements in one examination, including anterior and posterior corneal topography, corneal pachymetry, anterior chamber analysis, and scotop pupillometry. About 35,000 measuring points are captured in less than 0.2 seconds, which, according to LaserSight, significantly increases accuracy and eliminates the need for head strapping during the examination.

Our Doctors have been waiting for stereo topography for a long time. Stereo capability differentiates the ASTRAmax from any other topographer, and it gives us the truest rendering of the cornea to date.

Dr. Rosenbaum, Medical Director at Rosenbaum Eye and Laser Center and Asst. Clinical Professor at Michigan State Univ. College of Human Medicine states that topographers until now have basically look through a single camera down a tube to take a snapshot of the surface of the cornea to assess micro elevations and depressions.

#### ASTRAmax Adds depth

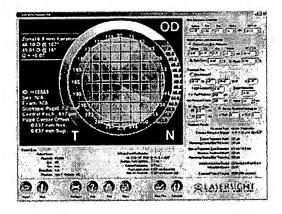
The problem is that we've been doing this without stereopsis, without any depth, and depth is what we're trying to measure. It's the peaks and valleys on the cornea that we're need to assess. The level of accuracy of our corneal measurement determines the level of accuracy of our surgical treatment. In monocular topographic instruments, the calibration of each point is based on the calibration of its near neighbor closest to the center. When you calculate point number one, you get an answer. But the calculation of point number two is based on what the machine came up with for point one.

The problem is that a slight inaccuracy in the center keeps compounding, getting worse and worse. Sing there are two views in stereo topography, each point on the cornea can be measured independently. points depend on any other points; each is calibrated uniquely.

Can this level of technical measurement sophistication be fully appreciated in the final surgical outcom

First of all, everything we do in laser surgery at Rosenbaum Eye and Laser Center assumes that we are measuring the shape and prescription of the cornea accurately. But now we have another fantastic too at our disposal to achieve this critical goal. In Laser Surgery, there may be times when the refractive procedure doesn't turn out well as perfectly as we'd like, resulting in irregularities of the cornea. Dr. Rosenbaum notes it is critical in these cases to assess the nature of these irregularities precisely in order to offer the best treatment.

'The excimer laser is accurate to one-quarter of a micrometer. however, as we move further and further out peripherally, even the slightest inaccuracy of monocular topography tends to compound, eventual causing us to be off by as much as 5 to 10 µm. Our diagnostic ability to measure the cornea hasn't bee matched to the precision of the laser, until now it's been the weakest link. Now, stereo topographic technology is going to move measurement accuracy to the same level of precision that we can now achieve with the laser at our Laser Center.



#### Checkerboard pattern

Instead of a conventional Placido ring, the ASTRAmax utilizes a black-and-white-checkerboard pattern. there's a slight rotation of tissue during the surgery, the conventional ring system may not pick it up accurately. Since there are no clock hours on the disks indicating rotation, this could be missed.

"The checkerboard Placido disc allows us to obtain both radial and tan-gential information. This means that we get information moving from the center outward, as well as moving around the circle. Being ab to pick up rotational changes gives us another level of precision and accuracy that no other system caldo.

#### Pachymetry

The built-in pachymeter of the ASTRA-max measures the thickness over the whole surface of the cornea 1/60th second, eliminating patient eye movement as a significant variable of inaccuracy. The unit's thre cameras (one located centrally, and one on each side) triangulate views of several narrow projected sl beams of light as they pass over the cornea.

The stereo cameras see the slit beams as they pass through various cross-sections of the cornea, very much like a parallele piped on a slit lamp, there are four beams of light: vertical, horizontal, one at 45°, and another at 135°. The cameras are able to determine precisely the thickness of every point the bear pass through.

The multi-point pachymetry readings will help differentiate keratoconus from benign contact lens warpage. Many contact lens wearers end up with an elevation of tissue on the lower part of their corne When you do pachymetry of this bump, if it's thin, then you know it's an ectasia. You can't remove any tissue there. But if the bump is not any thinner than a symmetrical point on the superior cornea, then you know that it's not an ectasia, and merely contact lens warpage. If the vision is 20/20, we can repair this with a standard treatment. If, however, the best vision with glasses is 20/30 or 20/40, we can then, using ASTRApro (software for the ASTRAmax) software, perform a custom ablation with the Laser, and smooth out the elevation.

This is why measurements must be so precise.

#### Pupil measurement

There are three main measurements surgeons want to know before treating the eye: The precise shape and power of the cornea. The thickness of the cornea. The size of the pupil under dimlight conditions. The ASTRAmax is designed to perform all three of these measurements with its built-in pupillary photopic and scotopic pupillometry device. The stereo topographer gives us the truest rendering of the cornea to dat

We've found that people who have a good quality of vision have a prolate shaped cornea. A prolate surface looks like the top of a football when viewed from its tip. This shape is opposed to oblate, which is like looking at the top curve of a football from the side of the ball. We've found that the prolate shape somehow relates to better perceived vision, so we've focused on preserving the cornea's prolate shape Preserving or restoring a prolate shape reduces the surgically induced higher order aberrations of the cornea. And this reduction is correlated with improved vision.

To put this aspherical strategy into practice, LaserSight has developed and tested a custom ablation system involving three elements: the AstraMax topographer, software called AstraPro and a new laser called AstraScan. The AstraMax, measures pupil size, asphericity and corneal contour to determine the best kind of postop cornea that preserves the prolate shape but also achieves the refractive correction This information is fed into AstraPro, custom ablation software that actually plans the surgery. Dr. Rosenbaum evaluates the AstroPro's surgical plan carefully, to make sure that enough corneal tissue will remain. Finally, when he's satisfied with the ablation profile, the surgical team puts the corneal data on a floppy disk and loads it into the laser.

The Rosenbaum Eye & Laser Center in Lansing, MI is currently using this technology to enhance patient laser surgery outcomes and evaluate both pre-operative eyes and any problematic eyes post-treatmer

# Research Sources Showing the Effect of Pupil Size on Vision

 Howard V. Gimbel, Ellen E. Anderson Penno, LASIK Complications: Prevention and Manageme Slack, Inc., ISBN 1556423926.

Chapter 2: Patient Selection and Preoperative Workup, Table 2-1 "Patients with large pupils need to be forewarned of the possibility of night vision difficulties. E important in high corrections. Corneal surgery may not be advisable."

Chapter 2 - Patient Selection and Preoperative Workup, p.17

"Pupil measurements may indicate that a patient will have night vision disturbances if the pupils a dilated in dim light, and those patients should be warned that they are at higher than average risk for effect of LASIK or PRK."

Patient Examples, p. 143

"Large pupil, Lasik surgery canceled...36-year-old-man...Cycloplegic refraction was -7.25/-0.75 OD © 0.5 OS...pupils of 4 mm in normal light and 8 mm. in dim light...he was counseled that considering pupils in dim light, he would be more likely to experience night vision difficulty and may find this disa elected after this discussion to cancel LASIK surgery."

 Jeffery J. Machat, Stephen G. Slade, Louis E. Probst, The Art of Lasik, 1999, 2nd Ed., Slack Ir 1556423861.

Preoperative Myopic and Hyperopic LASIK Evaluation, p. 131-2

"High myopes not only commonly have reduced best-corrected vision, but also night glare, and it is i to evaluate these candidates carefully, taking into account the corneal thickness, pupil size, and optical zone when counseling them."

Lasik Complications, p. 397

"Night glare is a result of a pronounced form of spherical aberration, with the pupil diameter in exceeding that of the effective optical zone created...Patients complain of halos, starbursts, and a reduction of qualitative vision in conditions of reduced illumination."

Lasik: Principles and Techniques, Lucio Buratto, Stephen F. Brint, 1998, ISBN 1556423713

Preparation for Surgery - Contrast Sensitivity and LASIK, p.41

"Recent studies demonstrate that as the pupil increases in size with increasing darkness, th corresponding decrease in the contrast sensitivity, particularly at the lower contrast."

Preoperative Pupillometry in LASIK, p. 41

"In order to provide a good refractive and visual outcome under all light intensities, it is necessary to an ablation with an optic zone proportional to the pupil diameter. As a result, the preoperative measure the pupil diameter under scotopic light is very important. Pupil diameter can be measured by a nomethods...In 10% of our patients, the scotopic pupillometry was greater than or equal to 7.0 mm; performing an operation on these patients may therefore be disadvantageous for both the patient surgeon."

Optical Zone, Pupil Diameter, and Requested Correction, p.92

"It is commonly known that the occurrence of halos and night glare can arise from the optical proportion governed by the size of the treatment zone and the pupil diameter in dim light conditions, presumably

the scotopic pupil dilates beyond the diameter of the optical surgical zone."

Ablation Zone, Pupil Diameter, and Requested Correction, p. 92

"The issue of ablation zone diameter (sometimes improperly called "optic zone") is certainly crucial in LASIK treatment. The appropriate ablation diameter has to be decided, taking into account parameters such as attempted dioptric correction, residual corneal thickness, and pupil diameter diameter can easily be measured using infrared pupillometers... They provide pupil diameter measured using conditions, which is the way pupillary diameter has to be measured, because of compatients regarding night vision when the pupil dilates. As a general rule, pupils measuring 6.0 mm in are very unlikely to have visual disturbances at night, at least for low to medium myopic correction pupils require larger ablation diameters to avoid visual disturbances, and higher attempted correction the same because of the greater light scattering that occurs at the ablation edge."

p. 226

"Glare, especially at night, is one of the greatest problems, seen more frequently in patients with lar and high corrections. The abrupt edge slope created in high corrections defracts light, thus inducing This complication is more important in those patients with unusually large resting pupil diameters. The pupil diameter should be measured preoperatively and the patient counseled based on this and the a planned correction. This complication is due to an accentuated form of spherical aberration, with the of the pupil under low luminance exceeding the effective optical zone created... Patients disproportionately large pupil compared to the optic zone should be avoided."

#### p.244 - Night Glare and Halos

"Night vision disturbances should be considered a very important side effect of laser surgery. The ricomplication must be screened pre-operatively through the measurement of pupil diameter, and a ablation strategies must be applied to minimize this side effect which, once occurred, is very difficult with... I personally have some patients who had to change their profession because they were unable at night after surgery...Once induced, these disturbances are very difficult to solve... Before surpreoperative visit should include pupil measurements under different light conditions... I personally following guidelines: Once a patient is found to have very large pupils in dim illumination (>7.0 discourage him or her from undergoing laser refractive surgery, or at least I inform him or her of the of night vision problems, regardless of the correction."

Preoperative Evaluation - p.125

"Measuring the size of the pupil in dim illuminations is important to avoid glare problems postoperative dim-light pupil diameter is more than 5 mm, such phenomena are to be expected and are more prothe greater the attempted correction."

Advanced Visual Function Testing in LASIK, p. 320

"Halos and visual loss at night may result from negative clearance, a condition where the pupil natura larger than the optical zone...To quantify the degree of negative clearance, accurate measurement of under dim (mesopic) conditions is required...If pupil diameters are accurately measured preop patients at risk of halos may be appropriately counseled or directed toward another procedure...In co it is incumbent upon practitioners to understand basic principles of vision testing, such as contrast s and have an appreciation for the mechanisms behind optical aberrations that arise from refractive procedures."

 Helen K. Wu, Roger F. Steinert, Peter S. Hersh, Stephen G. Slade, Vance M. Thompson, Refractive Thieme Medical Publishers, 1998, ISBN 0865777594.

Patient Selection and Preoperative Considerations, Ch. 2, p.45

"Pupil size becomes more relevant when considering refractive procedures in patients with very large low light conditions. These patients need to understand the increased risk of glare or halos and ma

future treatments that may provide for larger treatment zones."

Patient Selection and Preoperative Considerations, Ch. 2, p.45

"A basic extraocular muscle examination is performed to determine the presence of any abnormalitie function. Phorias or tropias and their symptoms can be complicated by refractive surgery... This is a that is much easier to deal with if handled prior to starting any refractive surgery, while making ce these patients are fully educated and aware of the uniqueness of their particular situation."

Dmitri T. Azar, M.D., Refractive Surgery, 1997, McGraw-Hill Publishing, ISBN 0838582761.
 Peter Hersh, J. Carr, Patient Evaluation for Refractive Surgery, Ch. 7, p. 102

"A patient with a mild degree of dry eye may be intolerant of contact lens wear and may reaso considered for a refractive procedure, although the added risk should be considered in deciding to such a procedure rather than correcting with spectacles."

p.108

"Measurement of the diameter of the entrance pupil in both light and dark conditions may identify pati have very large pupils, which may exacerbate edge effects of the optical zone following refractive profor example, glare, halo, and the starburst phenomenon).

Optics Rediscovered for the Keratorefractive Surgeon, p.119

"Size of the entrance pupil...should be estimated in brightly and dimly lit conditions. If the entrance larger than the optical zone in dim but photopic conditions, then an annulus of cornea surrounding the zone will transmit rays to the fovea."

Clinical Results of Excimer Laser Photorefractive Keratectomy for the Treatment of Myopia, p.441

"The primary determinants of the halo effect appear to be the ablation-zone diameter, pupil size, amount of induced refractive change. The halo effect after excimer laser PRK is generated by the d refraction of light through the treated (flattened) central cornea and the untreated (still myopic) paracentral cornea, which are normally blocked by the iris, now fall on the perifoveal retina and defocused annulus of light around the focused image on the fovea. This optical aberration results in blur circle superimposed on the corrected image from the central cornea. Therefore, under scotopic of when the pupil dilates, the halo effect tends to be more pronounced, particularly in patients with small zone diameters.

#### Articles

 Jack T. Holladay, MD, MSEE, Deep R. Dudeja, MD, Joanne Chang, OD, Functional Vision and Changes after LASIK determined by contrast sensitivity, Glare Testing, and Corneal Topography, J Cataract and Refractive Surgery, Vol. 25, May 1999, pp.663-669.

"Functional vision changes do occur after LASIK. The optical quality of the cornea is reduced asphericity becomes oblate. Changes in functional vision worsen as the target contrast diminishes pupil size increases. These findings indicate that the oblate shape of the cornea following LAS predominant factor in the functional vision decrease."

 Dr. Jack Holladay, MD, MSEE, FACS, Review of Ophthalmology, What We Should Really Tell LASIK May 1999.

"The problem with all excimer lasers on the market today is twofold. First, the engineers assumed cornea is spherical rather than prolate. Second, they assumed that their job was to reshape a relative sphere into a relatively flat sphere, rather than to reshape a steep prolate into a flatter prolate. As

excimer lasers actually reshape prolate corneas into what is known as oblate...This shape is actually worse than a sphere, because now the peripheral rays are bent even more powerfully than in the per a sphere, causing even more pronounced spherical aberration when the pupil dilates...This problem every patient who undergoes an excimer laser procedure to some extent."

• Brian S. Boxer Wachler, MD & Ronald R. Krueger, MD, MSE, Ophthalmology, Agreement and Repea Infrared Pupillometry and the Comparison Method, 2/99; Vol. 106, No. 2, pp. 319-23.

"In photorefractive keratectomy, there is an important relationship between the corneal ablation dian the pupil diameter. When the pupil dilates larger than zone of treatment, myopic blur is expected, wh reduce visual function... Even when the ablation zone equals the pupil diameter, off-axis light, such as light, may still cause glare... As glare has been shown clinically to be related to overall patient satisfar photorefractive keratectomy, attention to the patient's pupil diameter is important... the ablation diameter be no smaller than the noctumal pupil diameter to minimize glare and halos... There appears to be a accurately determining the pupil diameter in a dark environment as patients with pupils larger the should be counseled about the high risk of glare and halos or a larger ablation diameter may be select

- Ophthalmology Times, PRK, LASIK, Neck and Neck in Controlled, Matched Study, 2/15/99.
   "At one year, 12% of LASIK patients complained of visual disturbances at night compared with 6% patients."
- Ocular Surgery News, Pupil Measurement in Scotopic Light is Made Possible, 12/98.
   Michael Colvard, MD, Journal of Cataract and Refractive Surgery, Preoperative Measurement of Pupil Dilation Using an Office Pupillometer, 12/98.
- M. Alaa El Danasoury, MD, FRCS, Journal of Refractive Surgery, Vol. 14, 9/10/98, Prospective Bilate
  of Night Glare After LASIK with Single Zone and Transition Zone Ablation.
- Carlos E. Martinez, Raymond A. Applegate, Stephen D. Klyce, Marguerite B. McDonald, Jan P. Howard C. Howland, Effect of Pupillary Dilation on Corneal Optical Aberrations After PRK, Arc Ophthalmology, 8/98.

"Complaints of glare, halos, and disturbances of night vision after PRK probably result from chang corneal aberration structure induced by the laser ablation procedure. Because the eye lacks symmetry, the concept of spherical aberration is not strictly applicable to the eye. In studies of the opt eye, the concept of wavefront aberration is more appropriate...Our results indicate that PRK incre wavefront variance of the cornea and changes the relative contributions of coma-like and sphe aberrations to the total aberration...Larger attempted corrections, which result in deeper ablations an changes in corneal power from the treated to the untreated zones, are, as expected, correlated wit amounts of induced aberration."

 Peter Hersh, Edward E. Manche, Jonathan D. Carr, Weldon W. Haw, The Western Journal of I Excimer Laser Refractive Surgery, 7/1/98, Vol. 169, No.1.

"Complications of refractive surgical procedures such as PRK and LASIK can be considered primari or physical. Optical complications include glare, halo, decreased contrast sensitivity, and diplopia. Chalo symptoms are likely due to the optical effects of light passing through the border between central and peripherally untreated cornea. An eye with a larger pupil would be more likely to manifest the symplare and halo, especially at night when the pupillary diameter is greatest. Physical complications of LASIK include scarring, microbial keratitis, and sterile keratitis (infiltrates)...As the technology and te improve, we should develop a better understanding of the importance of laser-tissue interactions wound healing, and the role of pharmacologic agents in modulating refractive outcomes. These a should allow PRK and LASIK to become more predictable with fewer complications.

 William S. Nixon, Letters, Pupil Size in Refractive Surgery, Journal of Cataract and Refractive Surgery 12/97. "While it has come to my attention that many refractive surgeons screen for pupil size, it is also true to do not. Regardless, I do not believe there exists a shared set of guidelines used to determine the elipotential patients who, like myself, have both large pupils under low-light conditions as well as mo severe myopia. It is for the sake of these potential patients that I ask you to consider reporting on my others like it. Additionally, I ask the favor that my case be addressed because of my desperate need to any and all options that might allow me to again live a normal life."

 James J. Salz, MD, Night Vision and the Excimer Laser: How to Ensure Patient Satisfaction, Eyewor (available at www.eyeworld.org/nov97/450062.html)

At the 1997 Association for Research in Vision and Ophthalmology meeting in Fort Lauderd; researchers reported that up to 21% of patients who undergo laser correction complain of nic problems, which stem from reduced contrast sensitivity in low-lighting conditions, glare, and halos.

- Letter to the Editor, James Salz, MD -- Journal of Cataract and Refractive Surgery, Vol. 24, March 199
   "The need for pupillary testing in refractive surgery patients cannot be overemphasized...Individual pupil size that dilates beyond a given treatment zone... are at risk for heightened visual aberrations are be counseled carefully before the decision to proceed with surgery is made."
- Lamellar Refractive Surgery by J. Charles Casebeer, Luis Ruiz, Stephen Slade, SLACK Publishers, cc 1996.

Chapter 7 - The LASIK Procedure, page 102

"Poor night vision and other problems were found to be associated with small optical zones. At night, a patient's pupils are dilated beyond the zone of correction, so that the edges of the ablation are uncove Light coming into the eye is refracted from these edges, and halos are created around point sources of such as lamps."

- Peter Hersh, Results of Phase III Excimer Laser Photorefractive Keratectomy for Myopia, Ophthalmolc 10/97
- Col. Thomas H. Mader, MD, Bilateral PRK with Intentional Unilateral Undercorrection Performed on ar Pilot, Journal of Cataract and Refractive Surgery, Vol. 23, 3/97.

"Glare and ghost images, which have been well documented following PRK, may become even more prominent with increased pupil size. Optical zone diameters must be at least as large as the entrance preclude glare at the fovea and larger than the entrance pupil to preclude parafoveal glare. If a PRK pass fixates on a bright light source, out-of-focus light from the edge of the ablation area may form a halo ar image of the object. Thus, optical aberration at night following PRK may be especially bothersome."

• Mihai Pop, MD, Large Pupils Cause a Devilish Problem: Halos, Eyeworld, 11/96.

"Patients with refractive errors greater than -4D and scotopic pupils 8 mm or larger are contraindicated mm-zone excimer surgery...The onus is on the surgeon to choose the right patient...Not screening for patients preoperatively is a critical oversight on the part of the surgeon because these complications contemedied with currently available refractive techniques...There is no question these patients suffer hall starbursts during scotopic conditions. They cannot drive at night, and spectacles or contact lenses do a Currently the only treatment possible is instillation of 0.5% pilocarpine drops. Because these are relative young patients, they often have blurred vision lasting 90 minutes after instillation."

- Stephen Trokel, MD, Enlargement of the PRK Optical Zone, Journal of Cataract & Refractive Surgery,
- Peter Hersh, Jack Holladay, Corneal Optical Irregularity After Excimer Laser PRK, Journal of Cata Refractive Surgery, 3/96.
- Gregory Klonos, MD, John Pallikaris, MD, A Computer Model for Predicting Image Quality after PRK of Cataract and Refractive Surgery, 2/96.

- Yair Alster, Anat Loewenstein, Tami Baumwald, Isaac Lipshits, Moshe Lazar, Dapiprazole for Pati-Night Haloes After Excimer Keratectomy, Graefe's Arch. Clin. Exp. Ophthalmol, Vol. 234, 2/96, S139-5
  - "Haloes causing difficulties during night driving constitute one of the common complications of F presumed reason for this phenomenon is the different refraction of light through the treated and a areas of the cornea. Its magnitude is proportional to the ratio between the treated area and pupil size daytime, when pupil size is relatively small, the only rays reaching the retina are those entering the ablated zone of the cornea. At nighttime, the pupil dilates, and if it becomes larger than the ablated zone the treated and untreated area will reach the retina at different foci and thereby produce haloes."
- Richard S. Kalski, Comparison of 5-mm and 6-mm Ablation Zones in PRK for Myopia, Journal of F Surgery, 1-2/96.
- Ken Moadel, Excimer LASIK Under a Corneal Flap for Myopia of 2 to 20 Diopters, American Jophthalmology, 9/95.
- George J. Florakis, MD, Daniel A Jewelewicz, Heidi E. Michelsen, Stephen L. Trokel, MD, Evaluation Vision Disturbances, Journal of Cataract and Refractive Surgery, Vol. 10, 5-6/94, pp.333-338.
  - "...visual degradation experienced as halos or distinct rings of light may be attributed to a pupil diame is greater than the clear zone diameter after ablation. This is important because the diameter and plac the ablation zone may be limited by technical specifications of the laser performing the surgical proc by the surgeon's desire to limit the depth of ablation."
- David P.S. O'Brart, Excimer Laser PRK for Myopia: Comparison of 4 and 5 mm Ablation Zones, J Refractive and Corneal Surgery, 3-4/94.
- Calvin W. Roberts and Charles J. Koester, Optical Zone Diameters for Photorefractive Corneal Investigative Ophthalmology & Visual Science, 6/93.
- William S. Baron, Predicting Visual Performance Following Excimer PRK, Refractive and Corneal St 10/92.
- Raymond A. Applegate, OD, PhD & Howard Howland, PhD, Refractive Surgery, Optical Aberrati Visual Performance, Journal of Refractive Surgery, Vol. 13, 5-6/97.
  - ...refractive surgical procedures have focused on eliminating spherical and cylindrical defocus, important ocular optical aberration to correct. However, such an approach ignores the fact that the significant higher order aberrations. These naturally occurring higher order aberrations, combined v increases in the eye's higher order aberrations induced by refractive surgery, can decrease visual periodespite the elimination of spherocylindrical errors. Surgically induced higher order aberrations have entirely ignored but they have received less attention than the correction of defocus errors, despite the they are important to patient acceptance and to optimal visual performance.

Use of this Web Site is governed by this Terms of Use Agreement.

Surgical Eyes™ does not provide medical or legal advice. See <u>Terms of Use</u>.

©1998-2001 SurgicalEyes.com All rights reserved.

# Calculus with analytic geometry

HOWARD ANTON Drexel University

JOHN WILEY AND SONS New York Chichester Brisbane Toronto

#### QUADRIC SURFACES



Figure 15.8.1

In 2-space the general shape of a curve can be obtained by plotting points However, for surfaces in 3-space, point plotting is not generally helpful since too many points are needed to obtain even a crude picture of the surface. is better to build up the shape of the surface by using curves of intersection with some well-chosen planes. The curve of intersection of a plane and surface is called the trace of the surface in the plane (Figure 15.8.1). In Figure 15.8.2, we get an excellent picture of the surface  $z = x^3 - 3xy^2$  from the traces shown. (This surface is called a "monkey saddle" because a monkey sitting astride the x-axis has a place for its two feet and tail.)

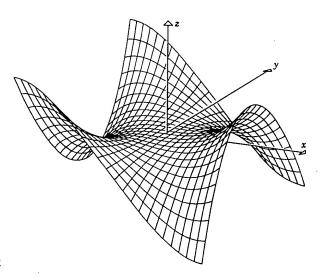


Figure 15.8.2

Earlier in the text, we saw that the graph in two dimensions of a second degree equation in x and y,

$$Ax^2 + Bxy + Cy^2 + Dx + Ey + F = 0$$

is a conic section. In three dimensions, the graph of a second degree equation in x, y, and z,

$$Ax^2 + By^2 + Cz^2 + Dxy + Exz + Fyz + Gx + Hy + Iz + J = 0$$

is called a quadric surface or a quadric.

Figure 15.8.3 shows the equations and graphs of six important quadre surfaces. In the equations, a, b, and c are positive constants. The states equations apply only when the quadric surfaces are in the positions shown

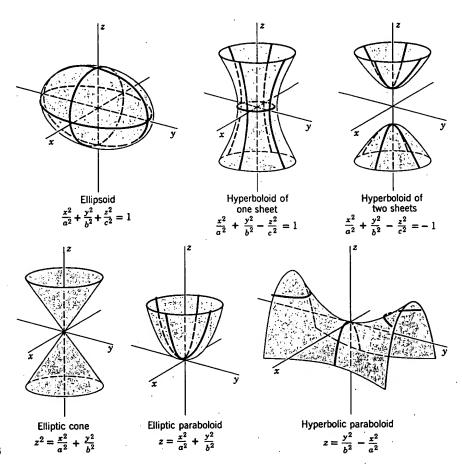


Figure 15.8.3

the quadric surfaces are rotated or translated from these positions, then the equations change. We will consider this point in more detail later.

The traces of the quadric surfaces in planes parallel to the coordinate planes are described in Table 15.8.1.

To study the traces of a quadric surface, we will need equations of planes parallel to the coordinate planes. The plane parallel to the xy-plane and passing through (0, 0, k) (Figure 15.8.5, page 868) consists of all points (x, y, z) with z = k. Thus the equation is

$$z = k$$

Similarly, x = k represents a plane parallel to the yz-plane and passing through (k, 0, 0), while y = k represents a plane parallel to the xz-plane and passing through (0, k, 0). The equation of the trace of a surface in the plane z = k is obtained by substituting z = k in the equation of the surface. Similarly, for traces in the planes x = k and y = k.

Table 15.8.1

Table 15.8.1			
SURFACE	NAME	EQUATION	
	ELLIPSOID	$\frac{x^2}{a^2} + \frac{y^2}{b^2} + \frac{z^2}{c^2} = 1$	
*	The traces in the coordinate planes are ellipse planes parallel to the coordinate planes.	es, as are the traces in	
	HYPERBOLOID OF ONE SHEET  The trace in the xy-plane is an ellipse, as are parallel to the xy-plane. The traces in the y are hyperbolas, as are the traces in planes	z-plane and xz-plane	
	HYPERBOLOID OF TWO SHEETS	$\frac{x^2}{a^2} + \frac{y^2}{b^2} - \frac{z^2}{c^2} = -1$	
	There is no trace in the xy-plane. In planes para which intersect the surface, the traces are elli xz-planes, the traces are hyperbolas, as are parallel to these.	pses. In the vz- and	

SURFACE	NAME	EQUATION
	ELLIPTIC CONE	$z^2 = \frac{x^2}{a^2} + \frac{y^2}{b^2}$
· · · · · · · · · · · · · · · · · · ·	The trace in the xy-plane is a point (the planes parallel to the xy-plane are eland xz-planes are pairs of lines interaces in planes parallel to these are	lipses. The traces in the yz- ersecting at the origin. The
	ELLIPTIC PARABOLOID	$z = \frac{x^2}{a^2} + \frac{y^2}{b^2}$
J. C.	The trace in the xy-plane is a point (the planes parallel to and above the xy-plane in the yz- and xz-planes are parabolas parallel to these.	ane are ellipses. The traces
	HYPERBOLIC PARABOLOID	$z = \frac{y^2}{b^2} - \frac{x^2}{a^2}$
	The trace in the xy-plane is a pair of line The traces in planes parallel to the xy hyperbolas above the xy-plane open in	-plane are hyperbolas. The

below in the x-direction. The traces in the yz- and xz-planes are

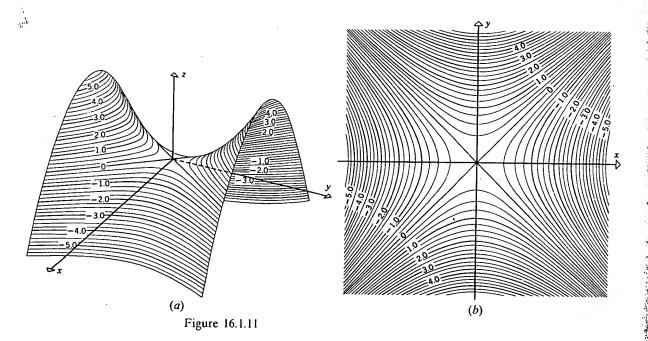
parabolas, as are the traces in planes parallel to these.

's in

ines lane

> ane, and

> ines



COMPUTER GRAPHICS (OPTIONAL)

In recent years, computer technology has been used to generate graphic representations of mathematical surfaces in three dimensions. The purpose of this brief section is to illustrate various forms of such computer graphics. It is not our objective to study this topic in detail, but simply to acquaint the reader with this extremely valuable tool.

**MESH PERSPECTIVES** A portion of a surface z = f(x, y) can be viewed in perspective and delineated by a rectangular mesh over a rectangular portion of the xy-plane. By altering program parameters, it is possible to change the section of surface shown, the point of view, and the apparent distance from the observer to the origin (Figure 16.1.12).

